

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: NATIONAL HOCKEY LEAGUE) MDL No. 14-2551
PLAYERS' CONCUSSION INJURY)
LITIGATION)

)

SUPPLEMENTAL AFFIDAVIT OF ANN C. MCKEE, M.D.

Now comes Ann C. McKee, M.D., who after being sworn, deposes and states that:

1. I am submitting this supplemental affidavit to address certain issues raised by the Honorable Susan Richard Nelson, United States District Judge, at the February 17, 2017 hearing to discuss the National Hockey League's subpoena to Boston University's Chronic Traumatic Encephalopathy Center.

THE NHL PLAYER DONORS

2. The CTE Center has analyzed approximately 350 brain specimens of former athletes (professional and amateur), military personnel, and others, and currently holds approximately 50 brain specimens that have not yet been analyzed. Of this group, we have studied a total of 5 brains of individuals who played hockey in the NHL. The NHL Subpoena, however, demands that we release the health information, interview notes with donors and their families, and material we created solely for the purpose of doing past, ongoing and future research studies (brain tissue slides, photographs and photomicrographs) for every single individual donor ("case") held by the CTE Center. The subpoena also seeks

drafts of published articles, communications with peer reviewers, and internal notes between and among scientists.

3. The NHL's first subpoenas to my colleague, Dr. Robert Stern, and me (issued in the fall of 2015) asked for "all documents" relating to NHL players and others. In response, my staff contacted the families of the NHL players whose brains had been analyzed. Four of the five families consented to the provision of "neuropathology reports, medical records, clinical interviews" and "other documents and emails associated with the case." These materials were provided.

4. The 2015 subpoenas did not request the primary data or research materials (photographs, photomicrographs, slides, etc.) that the NHL's October 2016 subpoena demands. We cannot produce these data for three of the four NHL donors¹ whose families authorized the Center to produce the more limited information identified in the preceding paragraph, for several reasons. First, the CTE Center does not have permission from donor families to produce these identifiable materials. I discussed this extensively in my initial affidavit and will not belabor the point here. The privacy and regulatory issues forbid the release of this healthcare information. In addition, these materials are our "work product" – Center scientists produced these data using the neuropathology skills unique to each Center scientist.

¹ I have been informed that the lawyers for the NHL and Boston University are working to establish a procedure for the League to review photographs and slides relating to the late Lawrence Zeidel, a party to this lawsuit.

WHAT DATA ARE REVIEWED DURING THE PEER REVIEW PROCESS?

5. I have been asked to clarify what information is reviewed during the peer review process. I understand that the Court is familiar with this process but to put my remarks in context it is necessary to describe it in some detail.

6. I am a co-author on more than one hundred “Original Research” publications, including approximately 13 papers for which I am the first author and approximately 16 papers for which I am the corresponding author. I am an ad hoc reviewer for eight journals, including (i) *Journal of Neuropathology and Experimental Neurology*; (ii) *Neurology*; (iii) *Annals of Neurology*; (iv) *Neurobiology of Aging*; (v) *Archives of Neurology*; (vi) *Brain Research*; (vii) *Acta Neuropathologica*; and (viii) *American Journal of Pathology*. Through these experiences, I am familiar with the peer review process from both a submitting author and a peer reviewer perspective.

7. The peer review process is designed to provide an unbiased, independent, critical assessment of a proposed research publication. It is considered an important extension of the scientific process that improves the overall quality and reliability of published work.

8. Journals differ in how they manage their peer review process. A majority of high impact medical journals follow the *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals* (known as the “Uniform Requirements”) of the International Committee of Medical Journal Editors (ICJME). Additional information about the ICJME can be found at <http://www.ICMJE.org>.

9. In my experience, the usual process of reviewing an Original Research paper following its initial submission begins with a review by the journal’s editors. If the paper is deemed appropriate for further consideration, the editors identify several external scientists

with subject matter expertise. Each peer reviewer is screened for professional, personal and financial conflicts of interest as related to the subject matter of the article to ensure the objectiveness of the evaluation. Peer reviewers are volunteers and are not compensated for their time or expertise, although in some instances they receive Continuing Medical Education (CME) credit. The review process is considered a prestigious undertaking and is viewed favorably in consideration for academic promotion.

10. Original Research manuscripts are submitted for review along with figures (images), tables and graphs that represent the primary data being presented and that the author intends to accompany the publication. Tissue slides are not submitted, because, as I noted in my earlier affidavit, they are one-of-a-kind, fragile, irreplaceable, “primary data” that contain tissue samples and are used in on-going research. Primary data, in this case “tissue” and “tissue slides,” must remain within the laboratory of origin. However, *photomicrographs and photographs* of the primary data (tissue slides) are submitted to journals.

11. Peer reviewers rely on the figures (photographs, photomicrographs), tables, graphs and accompanying text that is submitted to evaluate the quality, integrity, and importance of the research when deciding whether to recommend publication. The reviewers may ask for additional figures, tables, graphs – for instance, images from another part of the brain or spinal cord, or additional data on demographics. If the reviewers request this additional information, authors typically respond with additional images (or graphs, tables, text) that are appropriate to the request. On occasion, reviewers have asked me to provide copies of additional representative neuropathology photographs to be included in my manuscript.

12. In 30 years of academic publication, I have *never* been asked to produce primary data or the entire data set (described in my earlier affidavit at paragraphs 19 – 20) we have prepared for any case. No colleague of mine has ever been asked to produce primary data or the entire data set. In my field, I am aware of one instance in the past 30 years in which a researcher was compelled to allow other scientists to review the entirety of his project data, and that happened because the researcher was suspected of scientific fraud. This has never occurred in my work.

13. The representative images that accompany my manuscripts have been considered exhaustive and exemplary – indeed, an internet search for CTE reveals that most review publications, websites or general references to CTE - even if not authored by individuals from the CTE Center - use an image produced by my laboratory to demonstrate the disease.

14. In order to prepare this affidavit I went back to some of my recent publications to provide the Court with a more precise answer to the question of “how much data do reviewers actually look at?” A seminal paper I published in 2009 in the Journal of Neuropathology and Experimental Neurology, Chronic Traumatic Encephalopathy in Athletes: Progressive Tauopathy following Repetitive Head Injury, contained 35 images that represented the neuropathological data for 3 subjects. The extensive photographic documentation was critical to the novel observations on the tau pathology in CTE that was discussed in the paper. This paper has been cited 1151 times. In 2010, the same journal published a paper containing 38 images of slides and tissue samples that represented the neuropathological data for 12 subjects of which the data for 3 subjects were highlighted. Again, the extensive photographic documentation was critical to the novel observations

reported in the paper. This paper has been cited 355 times. In 2013 the journal Brain published an article titled The Spectrum of Disease in Chronic Traumatic Encephalopathy; it contained 35 photographs representing 85 subjects; the extensive photographic documentation was necessary to report the novel observations regarding the progression of pathological severity in the paper. This paper has been cited 671 times. In 2012, I was senior author on a paper in the journal Science Translational Medicine containing 58 photographs representing the data for 6 subjects and hundreds of mice. This paper has been cited 420 times.

15. My original affidavit (at paragraphs 9 and 11) refers to the 2015 and 2016 NIH consensus panel meetings of world-renowned neuropathologists. That group evaluated 40 CTE Center cases and reviewed more than 1500 images of slides and tissues samples – and confirmed all of my research conclusions. The digitized images of ~ 700 of my slides used by the 2015 consensus panel to define the criteria for the pathological diagnosis of CTE are freely available to anyone who would like to look at the primary data:

<http://www.ninds.nih.gov/research/tbi/ReportFirstNIHConsensusConference.htm>

If anything, my work tends toward *over-documentation* of the data with photographic images.

16. The Court asked for “peer reviewed reviews of peer reviewed literature” (Tr. p. 54) to determine the extent that reviewers have access to our data. Generally, the process journals apply to evaluate articles that review the research of others, referred to as “Reviews,” not “Original Research” articles, is far less rigorous than that followed for Original Research publications (all but one of the articles listed in Exhibit C to the NHL’s February 13, 2017 Reply Memorandum are “Reviews”). Review articles typically describe the “state of science” and may include, where appropriate, critiques of published work and independent

interpretations. No original research data, however, are reported as part of a review. If the subject is timely, Review articles are often solicited by a journal to encourage scientific debate or to increase readership to the journal. Review articles may or may not be peer-reviewed. If they are reviewed, the review process is less stringent and the criteria for publication is lower. Unfortunately, there is no easily-accessible database listing all the reviews of a publication containing original research.

17. A well-regarded publication may be cited by other scientists who publish their own research. Citations of this sort are a measure of the veracity of the primary work. A paper's "impact factor" reflects the number of times that a publication may be subsequently referenced and re-referenced. The impact factor is widely seen as a measure of a paper's (or a journal's) importance in a given field. It is contained in a bibliographic database maintained by the Institute for Scientific Information. See <http://wokinfo.com/> Although there is no database that specifically lists all the reviews of peer reviewed research papers, the impact factor of the original research publications coming out of the CTE Center is quite high and supports the conclusion that our published work has been widely accepted by the experts in the CTE field.

18. It is fair to conclude that my research has been subject to rigorous scrutiny – perhaps more than usual because of the cutting edge nature of the CTE Center's work and the public's interest in our findings – and has been validated in its entirety.

DONOR PRIVACY

19. At oral argument on February 17, Boston University's attorney showed the Court an email I had written in 2011, objecting to the premature release of the Center's

research conclusions regarding a former NHL player, an “enforcer” who had died in his mid-40s. Our analysis of his brain supported our conclusion that he had developed chronic traumatic encephalopathy, but I opposed releasing this information publicly before we had published our findings. However, the player’s widow and the leadership of the Sports Legacy Institute wanted the world to know what had happened to her husband:

<https://www.bu.edu/news/2011/03/03/probert-cte/>

DR. ROBERT CANTU’S ROLE IN THE CTE CENTER

20. In view of Dr. Robert Cantu’s participation as an expert in this lawsuit, I would like to clarify his role in the CTE Center. Dr. Cantu is a co-founder of the Sports Legacy Institute (now known as the Concussion Legacy Foundation). When that group’s collaboration with the Boston University Alzheimer’s Disease Center began in 2008, he was named one of four co-directors of the then-nascent Center for the Study of Chronic Traumatic Encephalopathy (now the CTE Center) and given a BU clinical faculty title. He is not, however, a neuropathologist; accordingly, he does not use a microscope in his practice or examine the brain tissue of deceased athletes whose brains are donated to the Center.

21. Dr. Cantu’s role does not provide him with access to my laboratory’s original research slides, photographs or any other data generated in the laboratories of my CTE Center colleagues. He participates in clinical discussions, but those discussions are conducted “blind” to any neuropathological findings and not dispositive – the final diagnosis relies solely on the neuropathological examination of brain tissue.

22. Dr. Cantu’s Boston University appointment does not come with any salary or specific research responsibilities. He does not speak for the University or the Center.

CONCLUSION

23. I remain concerned that the National Hockey League seeks the raw data the Boston University Chronic Traumatic Encephalopathy Center has created, and the drafts and internal communications relating to our publications, for the sole purpose of undermining my research simply because the plaintiffs are relying on it. I fear that if Center data are given to the NHL, it will not be scrutinized objectively, but rather, will be evaluated with a goal of exploiting immaterial discrepancies with a goal of tarnishing my reputation and that of the Center, rather than neutrally evaluating the veracity of my findings, which have already been subjected to rigorous scientific scrutiny. To my knowledge the NHL has not identified a single material flaw in Center research, or shown that it is biased, or that it lacks intellectual and scientific integrity. Had any of these issues been true, peer experts in the field would have identified them long ago, and certainly, my research would not be published, widely cited, and highly regarded. I strenuously object to the NHL's effort to damage my and the CTE Center's reputation solely to accomplish its goals in this lawsuit.

Further Affiant sayeth not.

Sworn and subscribed under the penalties of perjury.



ANN C. MCKEE, M.D.

Date: March 1, 2017